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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,887	11/04/2003	Steffen Nock	020144-002110US	6724

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EXAMINER

KIM, YUNSOO

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/701,887

Applicant(s)

NOCK ET AL.

Examiner

Yunsoo Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' remark filed on 5/23/06 is acknowledged.
2. Claims 25-27 are pending.
3. Applicant is required to update US priority in the first line of the specification and update status of the parent application. The update of the priority information filed 11/4/03 does not reflect the current status of the parent application. The application 09/881,814 has now been issued as U.S. Pat. No. 6,720,165B2.
4. It is noted that the description for Fig. 5 is missing from the specification of the instant application, p. 7-8.
5. In view of Applicants' arguments and remarks, the finality of the last office action has been withdrawn.
6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,099,005 (of record) in view of Kim et al. (Journal of Biol. Chem. 1994, vol. 269, pp. 12345-12350), newly cited, U.S. Pat. No. 6,358,710, newly cited, and Pierce Product Information for ImmunoPure IgG1 Fab and F(ab')_2 preparation kit, newly cited and U.S. Pat. No. 4,281,061 (of record).

The '005 patent teaches a method of making F(ab)_2 fragments from monoclonal antibody by treatment of sialidase (col. 5, lines 48-60, in particular) prior to protease treatment such as papain or pepsin to enhance the production of F(ab')_2 (col. 6, lines 34-40, in particular) and purification via Protein A-Sepharose CL-4B (col. 8, line 58-64, claims 1-8, in particular).

The '005 patent further teaches monoclonal antibody is a glycoprotein and carbohydrate moieties are generally bound to Fc region (col. 1, lines 51-64, in particular). Thus, the "glycosylated antibody" comprising a hinge region, the hinge region comprising protease cleavage sites and having non-hinge region adjacent to hinge region comprising oligosaccharides as claimed is an inherent property of monoclonal antibody.

The '005 patent does not particularly teach the kit, or use of glycosidase hydrolyzing N-glycosidic or O-glycosidic linkage between a sugar unit and an amino acid as claimed in claims 25-27.

However, Kim et al. teach the IgG molecules possess conserved glycosylation site at Asn-297 in the CH-2 (e.g. adjacent to hinge region) domain of heavy chains (see introduction, p. 12345, col. 1, in particular). Kim et al. further teach that the O-glycosylation renders the hinge region resistant against the proteolysis of the heavy chains (abstract, discussion, in particular). Further, generation of Fab/c was resulted from incomplete protease treatment (Fig. 4, discussion, in particular).

The '710 patent teaches the N-glycosidases and O-glycosidases are commonly used for deglycosylation of N-linked carbohydrates on protein molecules and O-linked carbohydrates on protein molecules, respectively (co. 19-21, overlapping paragraph, in particular).

Pierce Product information teaches that the proteases, purification system and instruction to generate IgG Fab and F(ab')_2 can be prepared as a kit.

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The '061 patent teaches the components or reagents can be provided as kits as a matter of convenience , optimization and economy of the users (see col 22, line 62 - col 23, line 4 in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute the sialidase treatment prior to a protease treatment in a method of making F(ab)'2 fragment as taught by the '005 patent with a N-or O-glycosidases as taught by the Kim et al. and the '710 patent and package the glycosidase, proteases, purification medium and instruction into a kit format as taught by the Pierce Kit and the '061 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because Kim et al. teach the glycosylation renders the hinge region resistant against the proteolyses of the heavy chains and the '710 patent teaches that the N-linked or O-linked carbohydrates can be removed from the protein molecules by N-glycosidase or O-glycosidase, respectively to make more susceptible to protease treatment to enhance F(ab)'2 fragment production. It is well known in the art to assemble the active ingredients in a kit format as taught by the Pierce product information for convenience, optimization and economy of the users as taught by the '061 patent.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claims are allowable.

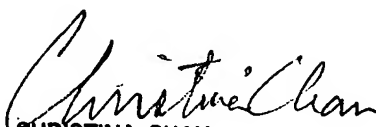
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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June 20, 2006


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